

Appl. No. 10/564,452
Reply to Final Office Action dated April 2, 2009

REMARKS

This Amendment is submitted in reply to the final Office Action mailed on April 2, 2009. The Office Action provided a three-month shortened statutory period in which to respond, ending on July 2, 2009. Accordingly, this amendment is timely submitted. No fees are believed due with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 0112701-00703 on the account statement.

Claims 1-15 are pending in this application. In the Office Action, Claims 1-2 and 5-15 are objected-to. Claims 1-2 and 5-15 are rejected under 35 U.S.C. §112. Claims 1-2 and 5-15 are rejected under 35 U.S.C. §103. Applicant does not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

In response, Claims 1, 5 and 10-15 have been amended and Claims 6-7 have been canceled without prejudice or disclaimer. The amendments do not add new matter. In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the rejections should be withdrawn.

In the Office Action, Claims 1-2 and 5-15 are objected to because the words "fibre" and "fiber" are used interchangeably. The Patent Office asserts that the term "fiber" should be spelled in English and used consistently among the claims. See, Office Action, page 2, lines 9-13. In response, Claims 1, 5 and 10-15 have been amended for clarification purposes to recite, in part, a source of dietary "fiber." The amendment does not add new matter. The amendment is solely for clarification purposes. For at least the above-mentioned reasons, Applicant respectfully submits that the objection to Claims 1-2 and 5-15 is now rendered moot.

Accordingly, Applicant respectfully requests that the objection to Claims 1-2 and 5-15 be reconsidered and withdrawn.

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In the Office Action, Claims 1-2 and 5-15 is rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Patent Office asserts that "there is no support for a source of dietary fiber comprising 30-60% insoluble fiber." See, Office Action, page 3, lines 6-7. In response, Applicant has amended Claims 1 and 10-15 to recite, in part, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas. The amendments do not add new matter. The amendments are supported in the specification at, for example, page 5, lines 26-31; page 9, lines 23-25. In view of the amendments to Claims 1 and 10-15, Applicant respectfully submits that the rejection of Claims 1 and 10-15 under 35 U.S.C. §112, first paragraph is now rendered moot.

Accordingly, Applicant respectfully requests that the rejection of Claims 1 and 10-15 under 35 U.S.C. §112, first paragraph be reconsidered and withdrawn.

In the Office Action, Claims 1-2 and 5-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over WO 02/39834 to Spivey-Krobath et al. ("Spivey-Krobath") in view of U.S. Patent No. 6,489,310 to Brassart et al. ("Brassart"). In view of the amendments and/or for at least the reasons set forth below, Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Currently amended independent Claim 1 recites, in part, a liquid or powdered and reconstitutable nutritional composition comprising about 4.5 to about 6g protein/100ml composition and a source of dietary fibre, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas. Currently amended independent Claims 10-15 recite, in part, methods comprising administering a composition comprising about 4.5 to about 6g protein/100ml composition and a source of dietary fibre, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas. The amendments do not add new matter. The amendments are supported in the specification at, for

example, page 7, lines 29-32; page 9, lines 23-25. Malnutrition or gastro-intestinal disorders, more generally gut-discomfort or pain, may simply be the consequence of unhealthy or unbalanced nutritional behavior. However, malnutrition may also affect perfectly healthy people, be it due to increased energy expenditure, as is the case with athletes or other sportsmen following intensive physical exercise, be it in other circumstances such as pregnancy. The occurrence of malnutrition in various situations during life, in particular with elderly or ill people, has thus led mainly to high calorie and high nutrient compositions. Consumption of such compositions, however, was often problematic, especially in patients with unbalanced gut flora and with gut impairment, because of gut pain or discomfort. See, specification, page 1, line 20-page 3, line 6.

Further, as is shown by the Example at pages 12-15, a composition including 4.5 to 6g protein/100ml composition, acacia gum as a soluble fiber in addition to an insoluble fiber and oligosaccharides demonstrated good shelf-stability for 8 months and was judged to have a good taste. The composition was also rich in fiber and improved intestinal transit, gut flora and gut comfort. See, specification, Example, pages 12-15. Therefore, the present invention provides a nutritional composition that has a high energy content and improves digestive tract health. The presently claimed compositions also provide the advantage of a surprisingly low viscosity that results from use of the claimed fiber blend. Despite the high proportion of soluble non-starch polysaccharides and oligosaccharides, and the high amount of total fiber of the compositions, the compositions have a surprisingly low viscosity and are surprisingly well-tolerated. In contrast, Applicant respectfully submits that the cited references are deficient with respect to the present claims.

Spivey-Krobath and *Brassart* both fail to disclose or suggest a nutritional composition comprising about 4.5 to about 6g protein/100ml composition and a source of dietary fibre, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 - 80 mPas as required, in part, by currently amended independent Claims 1 and 10-15. Instead, *Spivey-Krobath* is primarily directed toward a nutritional composition for the prevention or treatment of an immune condition. Indeed, the only

reference to specific amounts of protein at any place in *Spivey-Krobath* is in Table I on page 10 where it is specified that the composition contains either 10.5 or 7.0 g/100ml composition dependent on the desired energy content of the composition. See, *Spivey-Krobath*, Table 1. Further, *Spivey-Krobath* also fails to disclose or suggest the presently claimed viscosity. As such, *Spivey-Krobath* fails to disclose or suggest a nutritional composition comprising about 4.5 to about 6g protein/100ml composition and a source of dietary fibre, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas as required, in part, by currently amended independent Claims 1 and 10-15.

Brassart is entirely directed toward an enteral composition that contains a protein source, a lipid source, a carbohydrate source and a fiber blend. See, *Brassart*, Abstract. However, the only place in the disclosure of *Brassart* that discusses specific amounts of protein are in the examples, where 3.8g protein/100ml composition was used. See, e.g., *Brassart*, Example 1. Further, *Brassart* fails to disclose or suggest the presently claimed viscosity of the composition. At no place in the disclosure, however, does *Brassart* even mention a nutritional composition comprising about 4.5 to about 6g protein/100ml composition and a source of dietary fibre, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas as required, in part, by currently amended independent Claims 1 and 10-15.

The Patent Office asserts that “[g]iven that modified *Spivey-Krobath* et al. disclose a nutritional composition identical to that presently claimed, it is clear that the composition would inherently possess the recited viscosity.” See, Office Action, page 5, lines 16-19. However, Applicant respectfully disagrees because modified *Spivey-Krobath* clearly does not disclose the “identical” composition to that presently claimed. Instead, as Applicant has already pointed out, *Spivey-Krobath* and *Brassart* both fail to disclose the presently claimed compositions having certain protein amounts. Of course, the amount of protein contained in a composition can greatly affect the viscosity of the composition. Because the cited references fail to disclose or suggest

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each and every element of the present claims. Applicant respectfully submits that it is improper for the Patent Office to allege that the compositions of the cited references have viscosity ranges that are "identical" to the viscosities of the presently claimed compositions.

In fact, to satisfy the test for inherency, the Patent Office would be required to show that the compositions of *Spivey-Krobath* and *Brassart* necessarily (i.e., always or automatically) provide for compositions having a viscosity of about 30-80 mPas. That condition simply is not met under the present circumstances, especially in view of the fact that the claimed compositions and compositions of the cited references are not the same. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. See, MPEP 2112. *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

The Patent Office also asserts that "it would have been obvious to one of ordinary skill in the art at the time of the invention to have used acacia gum as the soluble fiber in the fiber blend of *Brassart* et al. because doing so would amount to nothing more than the use of a known soluble fiber source for its intended use in a known environment to accomplish entirely expected results." See, Office Action, page 5, lines 10-15. However, Applicant respectfully disagrees. In contrast, Applicant notes that, as discussed above, the Example in the specification at pages 12-15 clearly illustrates that the use of acacia gum as a soluble fiber, in addition to an insoluble fiber and oligosaccharides, in a nutritional composition demonstrated good shelf-stability for 8 months and was judged to have a good taste. The composition was also rich in fiber and unexpectedly improved intestinal transit, gut flora and gut comfort. See, specification, Example, pages 12-15. Further, in contrast to the Patent Office's assertion that the use of acacia gum results in "entirely expected results," Applicant respectfully submits that the cited references fail to even mention the unexpected benefits of improved intestinal transit, gut flora and gut comfort provided by use of the presently claimed composition. For at least the above-mentioned reasons, Applicant respectfully submits that *Spivey-Krobath* and *Brassart* fail to disclose each and every element of the present claims.

Accordingly, Applicant respectfully requests that the obviousness rejection of Claims 1-2 and 5-15 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

In the Office Action, Claims 1-2 and 6-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over *Brassart* in view of *Spivey-Krobath*. In view of the amendments and/or for at least the reasons set forth below, Applicant respectfully submits that the cited references are deficient with respect to the present claims.

As discussed above, currently amended independent Claim 1 recites, in part, a liquid or powdered and reconstitutable nutritional composition comprising about 4.5 to about 6g protein/100ml composition and a source of dietary fibre, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas. Currently amended independent Claims 10-15 recite, in part, methods comprising administering a composition comprising about 4.5 to about 6g protein/100ml composition and a source of dietary fibre, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas. In view of the amendments and/or for at least the reasons previously stated with respect to the rejection of Claims 1-2 and 5-15 under 35 U.S.C. §103(a) as being unpatentable over *Spivey-Krobath* in view of *Brassart*, Applicant respectfully submits that the cited references fail to disclose or suggest every element of the present claims.

For example, neither *Spivey-Krobath* nor *Brassart* disclose or suggest a nutritional composition comprising about 4.5 to about 6g protein/100ml composition and a source of dietary fibre, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas as required, in part, by the present claims. Instead, and as described above, *Spivey-Krobath* is primarily directed toward a nutritional composition for the prevention or treatment of an immune condition. See, *Spivey-Krobath*, Abstract. Similarly, *Brassart* is entirely directed toward an enteral composition that contains a protein source, a lipid source, a carbohydrate source and a fiber blend. See, *Brassart*, Abstract. At no place in the disclosure, however, does *Spivey-Krobath* or *Brassart* even mention a nutritional composition comprising about 4.5 to about 6g protein/100ml composition and a

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source of dietary fibre, wherein the source of dietary fiber comprises 20-40% by weight acacia gum, 30-60% by weight of insoluble non-starch polysaccharides and 20-40% by weight of oligosaccharides, wherein the composition comprises a viscosity of 30 – 80 mPas as required, in part, by the present claims. For at least the above-mentioned reasons, Applicant respectfully submits that *Spivey-Kroboth* and *Brassart* fail to disclose each and every element of the present claims.

Accordingly, Applicant respectfully requests that the obviousness rejection of Claims 1-2 and 6-15 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required, or credit any overpayment, to deposit account no. 50-4498 in the name of Nestle Nutrition.

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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